Title: Radical actions to address UK organ shortage, enacting Iran's paid donation programme: A discussion paper

Abstract:

Globally there is a shortage of organs available for transplant resulting in thousands of lives lost as a result. Last year in the United Kingdom (UK) 457 people died as a result of organ shortage[1]. NHS Blood and Transplant suggest national debates to test public attitudes to radical actions to increase organ donation should be considered in addressing organ shortage. The selling of organs for transplant in the UK is prohibited under the Human Tissue Act 2004. This discussion paper considers five ethical objections raised in the UK to paid donation, and discusses how these objections are managed within the only legal and regulated paid living unrelated renal donation programme in the world in Iran, where its kidney transplant list was eliminated within two years of its commencement.

This paper discusses whether paid living unrelated donation in Iran increases riskier donations, and reduced altruistic donation as opponents of paid donation claim. The paper debates whether objections to paid donation based upon commodification arguments only oppose enabling financial ends, even if these ends enable beneficent acts. Discussions in relation to whether valid consent can be given by the donor will take place, and will also debate the objection that donors will be coerced and exploited by a paid model. This paper suggests that exploitation of the paid donor within the Iranian model exists within the legally permitted framework. However paid living kidney donation should be discussed further and other models of paid donation considered in the UK as a radical means of increasing donation.

Keywords: Organ Donation, Transplantation, Kidney, Iran, Sale, Living Donation, Deceased Donation, Altruism, Consent. Exploitation

Introduction

-. Healthcare providers from an array of work environments are likely to encounter patients with end stage organ failure who could benefit from organ transplantation. Some patients however will not be transplanted due to a shortage of organs. Despite 126,670 organs transplanted globally in 2015, and an increase of 5.8% in comparison to 2014,[2~~1~~] there is still a reported need for even more organ transplants to save more lives**.** In the UK in 2017 despite performing a record number life saving transplants, 457 people died whilst waiting for a lifesaving transplant. [1~~2~~] Despite improvements in the last few years in organ donation rates in the UK ~~as~~ a result of the implementation of the Organ Donation Taskforce recommendations,[3] organ shortage remains a problem in the UK and globally.

. Plans to increase society's support organ donation were addressed by the NHS Blood and Transplant 2020 strategy[4] These strategies include the consideration of presumed consent in Wales, which was later enacted through The Human Transplantation (Wales) Act 2013 in 2015. [4]There are also plans outlined for Scotland and England to follow with opt--out polices. National debates to test public attitudes to radical actions to increase the number of organ donors was also proposed,

specifically to test public attitudes to whether those on the Organ Donor Register should receive higher priority if they needed to be placed on the transplant list . [4] The testing of public attitudes in incentivising donation with priority points when signing up to be a donor, was an activity undertaken within Israel prior to implementing legislation to enact this incentive in Israeli law.[5] There are however other incentives that could increase organ donation rates and are worth testing public support for. Three options have been suggested by Dworkin to increase the supply of available donors.[6] These options are described as first, donation as seen within the current altruistic donation system within the UK, second, conscription, as seen within deemed consent policies relevant to deceased donation, and finally, the sale of organs.[6] The aim of this discussion paper is therefore to explore the latter option of organ sales, as a means of increasing organ donation in the UK.

Organ donation in Iran

Whilst Iran has supported end stage kidney failure by providing renal dialysis services since 1974 renal transplantation seldom occurred for 20 years following its emergence, and between 1967 and 1985 only 112 related altruistic living donation (RALD) transplants were carried out in Iran. [7] This is said to be due to the 1979 revolution that caused Iranian assets to be frozen overseas and the Iran-Iraq war in the 1980s,[7] which virtually put a stop to transplantation for four years.[8] Whilst there are many provinces in Iran and limited reported renal data in English, the increasing demand for renal transplant in Iran can be seen by noting that in the province of Tehran alone, in 1991 there were just 587 people receiving haemodialysis, by 2006 there were 25,000 patients receiving haemodialysis .[7] During this time most transplants of Iranian citizens were from RALD and were performed in other countries, mostly the UK[9] [10] The Iranian Ministry of Health and Medical Education paid for these overseas transplants,[8] or used imported organs from Euro-transplant Organ Sharing Network which were of poorer quality to meet their transplant needs.[10] Unlike the UK, Iran is still only in its infancy in developing a deceased organ donation programme, in 2016 it still relied on living kidney donors to generate 43% of all kidney donors in Iran.[11] Goodzari [12] highlights some of the religious challenges that as a Muslim country, Iran has encountered. Religious scholars permission has had an essential role towards considerable developments in organ and tissue donation in Iran, some believing that the spiritual law of organ donation as within a fatwa, is superior to the law. It was only in the year 2000, that the Organ Transplant and Brain Death Act 2000 was approved by parliament in Iran to support the concept of neurological death legally, and enabling deceased donation following previous failures to enact it. [13] As a result of the increased number of patients in Iran needing transplants and the inadequate supply of altruistic kidney donors and long transplant waiting lists, thousands of patients died each year awaiting a renal transplant.[14] [11] Until 1988 all renal transplants performed in Iran were from unpaid RALDs, until a government funded paid and regulated programme known as the 'Gift of Altruism', 'Rewarded Gifting' financial incentive scheme was adopted for living unrelated donors (LURDs) which eliminated the renal transplant list within a few years of its commencement. [8-9] [15-18]

The current state of organ sales

When organ sales have been discussed, much of the focus has been on the evils of organ trafficking, such as human trafficking for the purpose of organ removal and organ tourism which occurs in illegal black markets. [19,20] Whilst organ sales can occur in many different forms, the most troubling is where living people have their organs stolen for cash value, or even worse, they are killed so that their organs can be removed and sold.[21] Another form is where people volunteer to sell one of their own organs to satisfy their desire for money and exercising their bodily autonomy. Regulated markets are argued to combat the evils associated with free and unlawful black markets, which are guilty of coercion, exploitation and lack of informed consent and appropriate donor care.[22]

In the UK a legal prohibition of the commercialisation of human organs was enacted within the Human Organs Transplant Act 1989 in response to an organ sales scandal which occurred within a black market in 1988 at the private Humana Hospital, in London. This Act was later repealed by the Human Tissue Act 2004, where both statutes prohibited any commercialisation in human organs intended for transplant. Whilst some believe that blanket prohibitions against organ commercialisation as seen within UK legislation, have been applied as a safeguard against abuse, it uses a sledgehammer to crack a potentially valuable nut. [22] Instead, regulation of a market could operate to safeguard against abuse by ensuring protection of vulnerable members of society, apply safeguards to ensure appropriate consent is given and any potential LURDs are not coerced in to selling.[23] By regulating and safeguarding an organ market, could open up a valuable source of life saving transplants which could address the organ shortage problem.

The main ethical objections to paid living donation were raised during the development of the Human Tissue Act 2004, [24] and are also acknowledged within the literature.[6 22,251]The several objections to paid living donation are (1)The body should not be treated as a means to an end commodity (2)The commercialisation of organs for transplant would increase risky donations (3)Commercialisation of organs should be prohibited because organs are non-regenerative (4)A trade in organs could cause harm to the vendor (5)Paid donation would reduce altruistic donations (6) Organ vendors would be exploited (7) Paid organ donors' consent would be invalid due to coercion and financial inducement influencing mental capacity. It is worth noting however that some of these objections to paid donation become problematic when we compare these to the current policy of unpaid living donations that are currently legally permitted, but donated within an altruistic programme. For example living kidney donors who donate to a relative, friend or via paired and pooled living kidney schemes, arguably also attain some degree of harm during the surgical procedure, and the kidneys are still permitted to be donated even though they too are also non regenerative. The paper therefore will concentrate on objections (1) (2) (5) (6) (7) and seeks to explore how these ethical objections are managed with within the Iranian programme.

Paid donation would reduce altruistic donations

Altruism has long been taken to be the guiding principle in the ethics of organ donation and has been used for justification in allowing or rejecting certain types of donation.[26] However it has been poorly defined in policy and position statements justifying some donations and used inconsistently in comparison to the philosophical literature on altruism.[27] Whilst altruism in organ donation has

been defined by both the motivation of the donor and the action of the donation, it is suggested that it is the motives of the donor that is of concern to transplant authorities in determining whether the donation will be altruistic.[28] Despite this proposal the Human Tissue Authority[29], the UK based regulator for Human Organs, whilst permitting and referring to varying forms of altruistic donations in its guidance, does not define altruism within its literature. Behaviour however is often described as altruistic when it is motivated by a desire to benefit someone other than oneself for that person's sake. It is argued that altruistic acts however need not involve self-sacrifice to enable them to be altruistic, where despite some gain being attained to person receiving the act, those undertaking the act attain some loss.[30] Instead acts and motives may remain altruistic even when they are performed from a mixture of motives, or of which are also self-interested.[30]

In understanding why reducing altruistic donations by the introduction of paid LURD would be so detrimental for social solidarity, a discussion in relation to our duties to altruism and society are worth considering. A better understanding however of our role in altruism is given by Wilkinson [21]who identifies with our responsibilities in society and its association with altruism, and suggests there are two forms. One form is obligatory and when there is a duty to rescue, and the second form is when altruism is supererogatory, morally good but not morally required. [21]In applying this in understanding of our role in altruism within organ donation per se, it can be suggested that if kidney donation was morally obligatory, then to demand money for a kidney or even refuse to donate would be wrong, but as this is supererogatory, to demand money for a kidney, may not be as good as giving it for free, but it wouldn't be wrong either. [21] Paid organ donation therefore in itself is argued to not violate the principle of the donation being altruistic because it is supererogatory.[21] It could also be suggested that to allow LURD donors, payment for this, could actually double altruism as the money used as a result of the donation could be used to help another person or a beneficent action. Payment for donation need not diminish altruism within a free donation system at all, people can still donate their kidney without payment and this could be seen as a purer form of altruism and attain the recognition of a greater act of beneficence. [31] There are no reasons why two renal donation programmes, one paid and one altruistic and unpaid, cannot exist simultaneously which would allow altruism to flourish.[31]

Despite both an altruistic and unpaid living and deceased donation programme, and a paid LURD programme existing simultaneously in Iran, it appears however that even 20 years later there is still an emphasis on LURDs to donate to help those in need of a life changing transplant.[32] Unpaid and altruistic deceased organ donation in Iran, unlike the UK has not been well established. Goodzari highlights some of the challenges that as a Muslim country, Iran has encountered in developing an altruistic deceased donation programme.[12] Whilst reluctance to participate in altruistic deceased donation has been based upon religious uncertainty requiring religious scholars' permission, it was only in the year 2000, that the Organ Transplant and Brain Death Act 2000 was approved by parliament to support the concept of neurological death legally, following previous failures to enact it.[13] This legislation allows legal diagnosis of death by neurological criteria which would enable an altruistic deceased organ donation programme to further develop. Organs for transplant other than kidneys during the early development of the transplant programme have remained scarce because there has been only a paid LURD programme for kidneys, and more recently living liver lobe donation.[18] Other organs than kidneys, for example, the donation of hearts, required a developed deceased programme and without this has resulted in many patient deaths as a result.[33] However by the end of 2012, there were 34166 kidney (including 4436 deceased-donor) and 2021 liver

(including 1788 deceased-donor), 482 heart, 147 pancreas, 63 lung, and several intestine and multiorgan transplants performed in Iran.[18] This demonstrates that altruistic deceased donations have increased whilst still enabling a paid donation programme to be in place. Whilst some suggest that since the adoption of the LURD model, the number of altruistic RALD donors have actually decreased, it is suggested that this is due to the elimination of coercive living related donor transplants occurring, now a LURD programme exists.[34,35]

Whilst altruism alone has not been enough to satisfy the growing need of kidney transplants in Iran, it was recognised by some transplant ethicists that the prohibition of all forms of financial incentives to organ donors, had resulted in patients' deaths and suffering worldwide .[16] Gillon elaborates on the dilemma of the pursuit of only altruistic donation at the detriment of substandard health provisions and lives lost as a result, and states when benefits in altruism and social solidarity can be obtained along with the maintenance of optimal healthcare, then we can all cheer. [36]However should the pursuit of altruism and social solidarity impair the provision of healthcare, many would give priority to optimal healthcare, even at the cost of more commerce and less altruism.[36~~35~~] The introduction of a trade in kidney donors has however raised its own ethical concerns particularly in relation to appropriate consent and coercion of potential donors.

The body should not be treated as a means to an end commodity

Deontological theories, as within Kantian ethics determine the morality of an act being dependent upon its conformity to some code of laws or norms,[37] whilst examples of acts deriving from deontology are often given as not lying, and keeping promises. Kant's second categorical imperative states, Act so that you treat humanity, whether in your own person or that of another, always as an end and never as a means only.[38] Morelli [39] identifies the appeal for this as a moral directive being based upon the strong rejection of using or exploiting another person for one's own purposes. Closely related to this is the directives requirement that we respect the humanity and dignity of another, but also the expression it gives to the significance of respecting one's own humanity.[39] Those arguing against this line of reasoning opposing paid donation, however do so by identifying that permitted unpaid altruistic donors are treated as a means to an end by enabling psychological and emotional benefits as a result of an unpaid donation,[40,41] however being the means to a paid donation is inaccurately considered morally dissimilar.

Beladi- Mousavi [42] identified the altruistic motivations of Related Altruistic Living Donors (RALDs) were due to a wish to help their relative, and this motive is also seen within other living donor studies.[40,41] Iranian RALDs relationships became strengthened with their relative following the donation of a kidney. [42] It therefore must be asked how using the body to allow some ends, such as strengthened relationships, to be pursued are morally permissible, whereas other ends are considered, as payment has been, are simply abhorrent. Morelli[39] explains the moral objection is not giving up the body part, but the body part for monetary gain rather than a beneficent purpose. Beneficent purposes however have found to coexist in addition to payment in a study which examined paid LURDs motives. [43]Thirty-seven per cent of 600 LURD~~'~~s identified their motive for donating was financial, however 60% of motives were altruistic, emotional and financial.[43] The

finances were used to fund variable beneficent actions such as medical costs to aid family in need of hospitalization, to maintain family reputation, solve personal problems, to pay back a debt, and to be exempted from the military service.[43] Examples of beneficent motives for payment have also emerged within the UK, with finances proposed to fund a child's cerebral palsy treatment.[44]

Paid organ donors consent would be invalid due to coercion and financial inducement influencing mental capacity

Ethical principles concerned with valid and appropriate consent in adults is well established in healthcare law internationally and embedded in both common law, and statute within the Mental Capacity Act 2005 in England and Wales. Valid consent must be given freely, without coercion, the person giving consent must have the mental capacity to do so, and the person giving consent must have been adequately informed about what they are giving consent to.[45] Two objections to commercialisation against kidney sales are based upon the suggestion that consent cannot be given by the vendor freely because they are coerced by their circumstances, and that prospective organ vendors are induced by the monetary element involved in the transaction.[25,46] Despite these objections informed consent however is suggested within the literature to be taken from the LURD, their next of kin, and donor identity is confirmed upon presentation of a national identity card in an attempt to prevent organ tourism and trafficking, a risk with any paid model. [47]

It can be quite hard for people to resist the offer of a large sum of money although in healthcare we do not normally consider a monetary element when taking consent from individuals[48] There are however many examples of healthcare where by individuals consent to do things involving money and their capacity to consent is not questioned because money is involved. Examples of these are when people agree and consent to going to work for money, and agree to buy or receive large sums of money when buying or selling property.[48] Bagheri [13] in favour of paid donation argues that kidney donors should be rightfully compensated, since everyone participating in the organ donation, the transplant surgeons, nurses, anaesthetists are all paid for their work, except for the donor. Determining the right amount of payment to be given to the donor appears vital in the debate exploring the ethical permissibility of financial incentive, too high a figure being considered too persuasive, but too little is exploiting. Despite dialysis costs in Iran estimated at an average annual cost of $11549,[49] and a transplanted kidney functioning in 75% of recipients at 5 years post transplant, [34] the costs saved on haemodialysis as a result of transplantation is profitable. The Iranian system despite this is cited to pay donors the equivalent of $1200 USD as a reward from the Government following their kidney donation, and is not enough to satisfy the majority of kidney donors requiring recipients to provide additional monetary rewarded gifts to the donors in an attempt to prevent exploitation.[9] If the recipient is poor then charitable organisations are stated to provide this top up payment.[9]

A further objection to organ sales is based upon the argument that poverty would coerce the donor in to selling their kidney.[17] Whilst coercion often results in exploitation and involves a technique that agents (coercers) use to get other agents (coerces) to do or not do something, and is typically thought to carry with it several important implications, in that it diminishes the targeted agent's freedom and responsibility, and that it is a violation of rights.[50] In arguing against this objection against commercialisation Wilkinson [21] suggests that it is only agents who can threaten and coerce

people, and although you could be threatened with poverty if you did not undertake an act that would alleviate poverty, poverty in itself cannot threaten a person. If we remove poor people out of the equation, and allow only the rich to sell their organs then this argument should vanish, but it does not.[21] In exploring the social class of LURD's in Iran it is evident that LURD donors have been of different social classes, it is not just the poor who have volunteered to donate within the paid model,[42] in fact some of the most vulnerable members of society, refugees, are treated with dialysis facilities within Iran but are not permitted to donate within the paid model to prevent organ trafficking.[10,15]

Organ vendors would be exploited

Exploitation is to take unfair advantage of another person, [51] and to use another person's vulnerability for one's own benefit, and can be transactional or structural in its origins.[52] Objections to exploitation are rooted in principles of justice and fairness, and can occur due to a failure of an agreement in reciprocity. I may for example obtain benefits from another person but do not pay them for this benefit when I agreed to do so.[53] The Iranian model attempts to prevent reciprocal exploitation of the donor and recipient, by once they are matched requiring the donor to signs a pledge, stating that the donor will not claim any monetary reward from the recipient during the laboratory tests and until after transplantation.[13] The recipient also signs a pledge not to compensate the kidney donor directly during this timeframe, [43]therefore preventing either donor or recipient revising or amending the agreement with requests for extra monetary compensation, or not donating the kidney following early payment. However in reality this form of exploitation appears to be evident. In a study by Zargooshi[54] refusal to realize preoperative promises to 51% of LURDs was evident. However in addition to the Rawlsian explanation of exploitation, exploitation can also occur when we turn to another's disadvantage to our advantage, using unequal bargaining power, that enables us to economically exploit others [53]. Goodin [53] identifies four characteristics of exploitative relationships being (1) The relationship embodies an asymmetrical balance of power (2) The subordinate party needs the resources provided by the relationship to protect their vital interests (3) For the subordinate party, the relationship is the only source of such resources (4) The superordinate party in the relationship exercises discretionary control over those resources. In exploring this further within the Iranian model it is evident that this model, endorsed by the Iranian government exhibits the 4th characteristic of Goodin's[53] proposition. Whilst it is alleged that since the compensation package in Iran is a fixed sum, donors have no opportunity to claim higher compensation for better Human Leucocyte Antigen (HLA) matching of donor and recipient,[7] which would enable better kidney transplantation, or higher payment for rare blood types which would reduce the waiting time for kidney transplant for those with rare blood groups. These in contrast however have been reported to occur.[55,56]On reviewing the literature this is possible for this to take place within the additional rewards given by the recipient at unsupervised meetings within the Dialysis and Patient Transplant Association (DAPTA) premises. [7,9]

The commercialisation of organs for transplant would increase risky donations

Objections to the commercialisation of human organs and tissues on the basis of this increasing the risk of donations, based their arguments upon the adverse effects of the paid blood donation system in the United States (US) in the 1970's-1980's, which resulted in contaminated blood products and infection of Hepatitis C and HIV in to thousands of people receiving blood transfusions in the US.

However more recently the UK whom also purchased blood products from the US during this time are now recognising that as many as 25,000 people in the UK have been infected with contaminated blood products from the US.[57] In 1970, it was estimated that up to one-third of U.S. blood centres depended on paid donors,[58] which recruited higher risk donors who were drug addicts and prisoners, often giving fictitious names and addresses to sell their blood to different blood banks.[58] Paid blood donors were also recognised to falsify their medical history in order to get paid for the donation due to the incentives that drove this,[58] as a result the United States now operates an unpaid approach to blood donation which is much tightly regulated and operated than that of the 1970's-1980's. The Iranian model addresses the ethical objection of paid donation causing risky donations by ensuring a complete medical and psychological check of the potential donor and recipient before donation and transplantation which is suggested to be in line with internationally agreed standards for care of the living donor. [9] It is suggested that this practice also rules out the possibility of persons with poor organs trying to cover up medical problems to participate in the programme,[35] which was an issue seen within a paid blood donation system in the United States.[59] Transplant recipients are also eligible for government provided medical insurance and come under the category of 'Patient with Special Diseases', this allows them to obtain immunosuppression drugs at no, or a subsidised cost.[9] In an attempt to reduce harm to the unrelated, living kidney donor, it is reported that they receive a year of health insurance and follow up care to enable them to recover.[9] It is however recognised that this is not regularly done and should be better organised.[60]

Conclusion

Whilst the Iranian model is not without its moral objections, there have been other proposals of paid donation models within the literature which address how an ethical paid and regulated living donation programme may exist.[61-64] Whilst many people will continue to oppose kidney sales regardless of the arguments offered and will feel that it is simply repugnant, we should not let this feeling of repugnance hold hostage to our moral thinking, for a great many things that we now hold in the highest esteem, including organ transplantation itself, occasioned strong repugnance in the past .[65]If we are going to deny treatment to the suffering and dying who need a transplant, which could be available through a paid and regulated donation programme, then we need better reasons than our own feelings of disgust if we are to continue to deny those awaiting a transplant, and those willing to sell, this opportunity.[66]

This paper has explored some of the ethical objections to paid donation raised during the development of the Human Tissue Act 2004, which outlaws the selling of organs for transplant within the UK. These objections have been discussed further within the context of the only legally permitted and regulated compensated living unrelated kidney donor model as adopted in Iran in 1988 in understanding some of the arguments within the paid donation debate. The paper has found that a regulated market for living kidney donors should not be completely disregarded and further discussion and testing of public support for such an initiative could help to address the UK organ shortage.

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